Senate

General Assembly

File No. 530

January Session, 2009

Substitute Senate Bill No. 1049

Senate, April 8, 2009

The Committee on Public Health reported through SEN. HARRIS of the 5th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT PROHIBITING CERTAIN GIFTS FROM PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES TO HEALTH CARE PROVIDERS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) *(Effective October 1, 2009)* As used in sections 1 to 5, inclusive, of this act:

(1) "Biologic" means a "biological product", as defined in 42 USC 262(i), as amended from time to time, that is regulated as a drug under the federal Food, Drug and Cosmetic Act 21 USC 301 et seq.;

(2) "Clinical trial" means a research project involving a drug or medical device that uses volunteer human research subjects to evaluate the safety or effectiveness of such drug or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition, or to evaluate the safety or efficacy of the drug or medical device in comparison with other therapies, and that has been approved by the federal Food and Drug Administration or has been approved by a duly constituted Institutional Review Board after

reviewing and evaluating such research project in accordance with the human subject protection standards set forth at 21 CFR 50, 45 CFR 46, or an equivalent set of standards of another federal agency;

(3) "Health care provider" means a person licensed under title 20 of the general statutes who may prescribe, dispense and administer drugs, or an officer, employee, agent or contractor of such person acting in the course and scope of such person's employment, agency or contract related to, or in support of, the provision of health care, but excludes an employee of a pharmaceutical or medical device manufacturer;

(4) "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent or other similar or related article, including any component, part or accessory, that is: (A) Recognized in the United States Pharmacopeia-National Formulary, or any supplement thereto; (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in persons or animals; or (C) intended to affect the structure or function of the body of a person or animal, and that does not achieve its primary intended purposes through chemical action within or on such body and that is not dependent upon being metabolized for the achievement of its primary intended purposes;

(5) "Pharmaceutical or medical device manufacturing company" means any entity that does business, either directly or indirectly, with the state as relates to the purchase of, or the provision of reimbursement for pharmaceuticals, biologics or medical devices, utilized in connection with a state program, including, but not limited to, the Medicaid program, state-administered general assistance program, HUSKY Plan, Part A or Part B, Charter Oak Health Plan, the Department of Correction's inmate health services program and the state employee health insurance plan and is engaged in (A) the production, preparation, propagation, compounding, conversion or processing of legend drugs, biologics or medical devices, either directly or indirectly, by extraction from substances of natural origin,

or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (B) the packaging, repackaging, labeling, relabeling or distribution of legend drugs, biologics or medical devices; but excluding a hospital, as defined in section 19a-490 of the general statutes, or a pharmacy licensed pursuant to section 20-594 of the general statutes;

(6) "Legend drug" means a drug that is required by any applicable federal or state law to be dispensed pursuant only to a prescription or is restricted to use by prescribing practitioners only, or means a drug that, under federal law, is required to bear either of the following legends: (A) "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DRUG FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN"; and

(7) "Research project" means a project that constitutes a systematic investigation designed to develop or contribute to general knowledge when the results of such project can be published freely by the investigator and such project reasonably may be considered to be of significant interest or value to the scientific community or health care providers working in the particular field of inquiry.

Sec. 2. (NEW) *(Effective October 1, 2009)* No pharmaceutical or medical device manufacturing company shall provide or pay for any food or beverage, or both, to any health care provider. Nothing in this section shall prohibit a continuing medical education provider or conference or meeting organizer from allocating any financial support provided by a pharmaceutical or medical device manufacturing company for the event to pay for food or beverage, or both, for all participants in accordance with the provisions of subdivision (3) of subsection (d) of section 3 of this act.

Sec. 3. (NEW) *(Effective October 1, 2009)* (a) Except as provided in subsection (d) of this section, no pharmaceutical or medical device manufacturing company shall provide or pay, either directly to a

health care provider or indirectly to an event sponsor, for the costs of travel, lodging, time spent or other personal expenses of such health care provider as relate to the attendance of such health care provider at any continuing medical education event, third-party scientific or educational conference or a professional meeting.

(b) A pharmaceutical or medical device manufacturing company shall separate all continuing medical education grant-making functions in the state from the sales and marketing departments of such company. Any decision concerning grants shall be made without regard to the sales and marketing objectives of the company.

(c) A pharmaceutical or medical device manufacturing company shall not provide any advice or guidance to a continuing medical education provider, even if such advice or guidance is requested by the provider, concerning the content or faculty for a particular continuing medical education program in the state that is funded by such company.

(d) Nothing in this section shall prohibit a pharmaceutical or medical device manufacturing company from providing or paying for:

(1) Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows and other health care professionals in training to attend educational conferences, provided: (A) The educational conference is a major educational, scientific or policy-making meeting of a national, regional or specialty medical association; (B) the selection of individuals who receive funds is made by the academic or training institution; and (C) no grants, scholarships, subsidies, support, consulting contracts or educational or practice related items are provided or offered to an individual attending such conference in exchange for prescribing, disbursing or using legend drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing or using legend drugs, biologics or medical devices;

(2) Compensation or reimbursement to a health care provider

serving as a speaker or providing such other actual and substantive services as a faculty organizer or academic program consultant for a continuing medical education event, third-party scientific or educational conference or professional meeting, provided the payment: (A) Is reasonable; (B) is based on fair market value of the services actually rendered by the health care provider; and (C) complies with the Accreditation Council for Continuing Medical Education's Standards For Commercial Support, or equivalent commercial support standards of the relevant continuing education accrediting body;

(3) Sponsorship or payment for any portion of the costs of a third-party scientific or educational conference, charitable conference or meeting or professional meeting, where (A) the payment is made directly to the conference or meeting organizer; (B) responsibility for and control over the selection of content, faculty, educational methods, materials and venue belongs to the organizer of the conference or meeting in accordance with the organizer's written guidelines; (C) such conference or meeting is held in a venue that is appropriate and conducive to informational communication and training about medical information; (D) such conference or meeting is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse with at least one educational presentation being the primary reason for the gathering; and (E) the main purpose for bringing attendees to such conference or meeting is to further their knowledge on the topic or topics being presented; and

(4) Sponsorship or other form of payment for any of the costs of a continuing medical education event provided such sponsorship or payment meets the Accreditation Council for Continuing Medical Education's Standards For Commercial Support or equivalent commercial support standards of the relevant continuing education accrediting body, and that no such sponsorship or payment is made directly to a health care provider.

Sec. 4. (NEW) *(Effective October 1, 2009)* (a) Except as provided in

subsection (b) of this section, no pharmaceutical or medical device manufacturing company shall: (1) Provide a health care provider with entertainment or recreational items of any value, including, but not limited to, tickets to performing arts or sporting events, theater, sporting equipment or leisure or vacation trips; (2) make cash or cash equivalent payments of any kind to a health care provider, either directly or indirectly; (3) provide a health care provider with tangible items of any value other than those permitted pursuant to this section and sections 2 and 3 of this act; (4) provide a health care provider with any grants, scholarships, subsidies, consulting contracts or educational or practice related items in exchange for prescribing, disbursing or using legend drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing or using legend drugs, biologics or medical devices; or (5) provide a health care provider with remuneration, in cash or in kind, directly or indirectly, that is prohibited under applicable state or federal law, including, but not limited to, section 53a-161d of the general statutes, and 42 USC 1320a-7b, including any rebate or kickback.

(b) A pharmaceutical or medical device manufacturing company may: (1) Provide reasonable compensation for the professional or consulting services of a health care provider in connection with a research project or clinical trial, or reimbursement of other reasonable out-of-pocket costs incurred by such health care provider directly as a result of the performance of such services, where the compensation or reimbursement is specified in, and paid for under, a written agreement; (2) provide reasonable compensation for expenses, including, but not limited to, travel and lodging, necessary for technical training of health care providers on the use of a medical device where the compensation is specified in, and paid for under, a written agreement; (3) provide, distribute, disseminate or receive peer reviewed academic, scientific or clinical information; (4) purchase advertising in peer reviewed academic, scientific or clinical journals; (5) provide legend drugs or medical device demonstration and evaluation units or educational materials concerning such drugs or units to a health care provider for the beneficial use and education of a

health care provider or the patients of such provider; (6) provide price concessions, such as rebates or discounts, consistent with the lawful general practice of the manufacturer or the industry; (7) provide information regarding legend drugs or medical devices, including: (A) Identification of appropriate coverage, coding or billing of such drugs and devices; (B) identification of computerized applications that support accurate and responsible billing to Medicare and other payors for such drugs and devices; and (C) information designed to offer technical or other support concerning the appropriate and efficient use or installation of such computerized applications, provided such technical or other support is not offered for the purpose of inducing a health care provider to purchase, lease, recommend or use such computerized applications; (8) provide payments or free outpatient legend drugs to health care providers for the benefit of low income individuals through an established patient assistance program, provided such program meets the criterion for a permissible program described in Advisory Opinion No. 06-03, issued by the United States Department of Health and Human Services Office of the Inspector General on April 18, 2006, or is otherwise permitted under applicable federal law and regulation including 42 USC 1320a-7b; (9) provide reasonable compensation, based on the fair market value, to a health care provider for consulting services, including, but not limited to, (A) research; (B) participation on a health care related advisory board; (C) collaboration with a nonprofit organization under the provisions of Section 501(c)(3) of the federal Internal Revenue Code of 1986, or any subsequent corresponding internal revenue code of the United States, as from time to time amended, dedicated to the promotion of health and the prevention of disease; and (D) presentations at training programs sponsored by a legend drug or medical device manufacturer, including education and training required by the federal Food and Drug Administration, concerning the development of safe and effective medical devices, where the compensation and reimbursement is specified in, and paid for pursuant to a written agreement. Such written agreement shall document the legitimate need for the consulting services and identify in advance of the

provision of such consulting services the connection between the competence and expertise of the health care provider and the services rendered under the agreement. The number of health care providers retained for such project shall not be greater than the number reasonably necessary to achieve the identified purpose. The entity contracting with the health care provider for such consulting services shall maintain records concerning the consulting services and shall make appropriate use of such services. The venue and circumstances of any meeting related to the provision of consulting services shall be conducive to the consulting services and activities related to the services shall be the primary focus of the meeting; or (10) provide reasonable compensation to a health care provider, based on fair market value, for the licensing of intellectual property where the compensation and reimbursement is specified in, and paid for under, a written agreement.

Sec. 5. (NEW) (*Effective October 1, 2009)* If a pharmaceutical or medical device manufacturing company provides compensation or reimbursement to a health care provider, in accordance with the provisions of subdivision (2) of subsection (d) of section 3 of this act or subsection (b) of section 4 of this act, and such compensation or reimbursement exceeds one thousand dollars for the calendar year, such company shall disclose, on a form prescribed by the office of the Attorney General, the aggregate compensation or reimbursement provided by such company to the health care provider during the calendar year. The information provided on such form shall include, but not be limited to, the name, address and institutional affiliation of the health care provider and a description of the reason for such payment. Such form shall be filed electronically with the office of the Attorney General on or before July 1, 2010, and annually thereafter, in a format that allows for the searching of individual health care providers or institutional affiliation. The office of the Attorney General shall, within existing budgetary resources, make available on its web site the information contained in such forms.

Sec. 6. (NEW) *(Effective October 1, 2009)* A violation of any provision

of sections 2 to 5, inclusive, of this act shall constitute an unfair and deceptive trade practice under subsection (a) of section 42-110b of the general statutes.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2009*	New section
Sec. 2	*October 1, 2009*	New section
Sec. 3	*October 1, 2009*	New section
Sec. 4	*October 1, 2009*	New section
Sec. 5	*October 1, 2009*	New section
Sec. 6	*October 1, 2009*	New section

PH *Joint Favorable Subst.*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 10 $	FY 11 $
Consumer Protection, Dept.	GF - Revenue Gain	Potential	Potential

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill results in a potential revenue gain to the state through violations of the Connecticut Unfair Trade Practices Act (CUTPA). The number of violations associated with the bill is anticipated to be minimal and therefore there is no cost impact upon the Department of Consumer Protection.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

OLR Bill Analysis

sSB 1049

AN ACT PROHIBITING CERTAIN GIFTS FROM PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES TO HEALTH CARE PROVIDERS.

SUMMARY:

This bill prohibits pharmaceutical and medical device companies that do business with the state from giving certain health care providers cash, gifts, or other things of value. It makes numerous exceptions to this ban, including permitting payments for students and providers attending meetings; providers performing research, clinical trials, or consulting work; and educational conference organizers.

The bill requires drug and device companies that pay a provider $1,000 or more a year to disclose certain information to the Attorney General's Office. It makes a violation of any of its provisions an unfair and deceptive trade practice.

EFFECTIVE DATE: October 1, 2009

ENTITIES AND PROVIDERS SUBJECT TO THE GIFT BAN

Pharmaceutical and Medical Device Companies

A drug or medical device manufacturer must meet two sets of conditions to be affected by the bill—its business activities and its relationship to the state. The bill applies to any entity, except a licensed hospital or pharmacy, that (1) produces, prepares, propagates, compounds, converts, or processes prescription drugs, "biologics," or medical devices or (2) packages or repackages, labels or relabels, or distributes them. A biologic, under the bill, is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of a human disease or condition.

Such an entity must also directly or indirectly do business with the state relating to purchasing or providing reimbursement for drugs, biologics, or medical devices in any state program including Medicaid, HUSKY A or B, state administered general assistance, Charter Oak, the Corrections Department inmate health services program, and state employee health insurance. The state also purchases veterinary drugs for the UConn Agricultural School, so the bill appears to apply to manufacturers of drugs and medical devices for animals (Since the definition of biologics applies only to human, the bill would not apply to a company producing biologics only for animals.)

Health Care Providers

The bill applies to licensed health care providers who can prescribe, dispense, or administer drugs. Physicians and physician assistants, dentists, podiatrists, optometrists, veterinarians, and advanced practice registered nurses can perform all these tasks; registered nurses and nurse-midwives can administer prescription drugs. The bill also applies to these providers' employees, officers, or agents when acting in the course of their relationship with the provider or in support of health care provision. But it does not include any employee of a drug or medical device manufacturer.

PROHIBITED ACTIVITIES

The bill prohibits a covered drug or medical device manufacturer from giving:

1. any food or beverage to a covered provider or paying for it;

2. or paying for, directly or indirectly to a provider or indirectly to the event sponsor, the costs of a provider's travel, lodging, time, or personal expenses at a continuing medical education (CME) event, third-party scientific or educational conference, or professional meeting;

3. any advice or guidance to a CME provider about the content or faculty for a program in Connecticut the company funds, even if the provider asks for it;

4. a provider any entertainment or recreational items, including tickets to sporting or performing arts events, sports equipment, or leisure or vacation trips;

5. any cash or cash equivalent payments to a provider, either directly or indirectly, or any tangible items of value other than those the bill permits;

6. a provider any grants, scholarships, subsidies, consulting contracts, or educational or practice-related items in exchange for the provider's prescribing, disbursing, or using prescription drugs, biologics, or devices or agreeing to continue to do so; and

7. a provider, directly or indirectly, remuneration, in cash or in kind, including any rebate or kickback that is prohibited under state or federal laws.

The bill requires a covered drug or device company to (1) separate all its CME grant-making functions in the state from its sales and marketing department and (2) make CME grant decisions regardless of its sales and marketing objectives.

PERMITTED ACTIVITIES

Payments to Providers

The bill permits covered companies to:

1. pursuant to a written agreement, (a) reasonably compensate providers for professional or consulting services related to a research project or clinical trial or (b) reimburse providers for any out-of-pocket costs they incur in performing research or clinical trials;

2. pursuant to a written agreement, provide reasonable compensation for providers' expenses, including travel and lodging, in obtaining technical training in the use of a medical device;

3. provide, distribute, disseminate, or receive peer-reviewed

academic, scientific, or clinical information;

4. purchase advertising in peer-reviewed journals;

5. provide prescription drug or medical device demonstration and evaluation units and educational materials about these products to providers for their or their patients' benefit;

6. provide rebates, discounts, and other price concessions consistent with their general practice or the industry's;

7. provide information about prescription drugs and medical devices including (a) identifying appropriate coverage, coding, and billing for the products, (b) identifying computerized billing applications and information and support about their use and installation, as long as the support is not intended to induce providers to acquire, recommend, or use an application;

8. provide samples of, or pay for, prescription drugs for low-income people through an established patient assistance program that meets federal criteria or is otherwise permitted under federal law; and

9. pursuant to a written agreement, reasonably compensate providers, based on the fair market value, for licensing intellectual property.

The bill also allows covered companies to reasonably compensate a provider, based on fair market value, for consulting services such as (1) research, (2) participating on a health care-related advisory board, (3) collaborating with a nonprofit organization that promotes health and disease prevention, and (4) making presentations at training programs a covered company sponsors, including those required by the Food and Drug Administration. The compensation must be paid pursuant to a written agreement that documents the legitimate need for the consulting services and identifies the connection between the provider's competence and expertise and the services he or she will perform. The number of providers contracted for a project cannot

exceed the number reasonably needed to achieve its identified purpose.

The entity contracting with a provider for these consulting services must make appropriate use of the services and keep records about them. The place and circumstances of any meeting held related to the consulting services must be conducive to consultation, and the activities related to consulting must be the primary focus of the meeting.

Payments Related to CME, Scientific or Educational Events, and Professional Meetings

The bill permits covered companies to provide or pay for various activities related to CME events, third party scientific or educational events, and professional meetings, under certain conditions.

It permits companies to provide scholarships or other financial aid to permit medical students, residents, fellows, and other health care students to attend educational conferences if:

1. the conference is a national, regional, or specialty medical association's major educational, scientific, or policy-making meeting;

2. the student's school or training institution selects the fund recipients; and

3. no one attending the meeting receives grants, scholarships, subsidies, support, consulting contracts, or educational or practice-related items in exchange for prescribing, disbursing, or using prescription drugs, biologics, or devices or agreeing to continue to do so.

It permits companies to compensate or reimburse a provider for speaking or providing actual and substantive services as a faculty organizer or academic program consultant at a CME event, third party scientific or educational event, or a professional meeting if the payment:

1. is reasonable,

2. based on fair market value for the services rendered, and

3. complies with the Accreditation Council for Continuing Medical Education's Standards for Commercial support or the relevant continuing education accrediting body's commercial support standards.

The bill permits companies to sponsor or pay for any portion of a third party scientific or educational event, charitable conference or meeting, or professional meeting if:

1. payment is made directly to the event organizer;

2. the organizer is responsible for and controls selection of the event's venue, content, faculty, educational methods, and materials and does so in accordance with its written guidelines;

3. the event venue is appropriate and conducive to conveying medical information and training;

4. the main purpose in bringing people to the event is to further their knowledge of the topics being presented; and

5. the event's primary purpose is to present at least one educational program and its time and effort is dedicated primarily to promoting scientific and educational activities and discourse.

The bill permits companies to financially support any costs of a CME event if (1) their support meets the Accreditation Council for Continuing Medical Education's Standards for Commercial Support or the relevant continuing education accrediting body's commercial support standards and (2) they do not directly pay or sponsor a health care provider.

DISCLOSURE

Any covered company that compensates or reimburses a provider

more than $1,000 in a calendar year must disclose certain information to the Attorney General's Office, on a form the attorney general prescribes. It must disclose (1) the provider's name, address, and institutional affiliation; (2) the provider's aggregate compensation or reimbursement; and (3) the reason for the payment. The company must file the form electronically beginning by July 1, 2010 and annually thereafter (apparently even if it no longer compensates any provider above the threshold level.) The form's format must permit searches by provider name or institutional affiliation. The Attorney General's Office must, within available resources, make the information it receives available on its website.

PENALTIES

The bill makes any violation of the payment and gift prohibitions or the disclosure requirements an unfair or deceptive trade practice.

BACKGROUND

Connecticut Unfair Trade Practices Act (CUTPA)

The law prohibits businesses from engaging in unfair and deceptive acts or practices. CUTPA allows the Department of Consumer Protection commissioner to issue regulations defining what constitutes an unfair trade practice, investigate complaints, issue cease and desist orders, order restitution in cases involving less than $5,000, enter into consent agreements, ask the attorney general to seek injunctive relief, and accept voluntary statements of compliance. It also allows individuals to sue. Courts may issue restraining orders; award actual and punitive damages, costs, and reasonable attorneys fees; and impose civil penalties of up to $5,000 for willful violations and $25,000 for violation of a restraining order.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute
Yea 21 Nay 9 (03/20/2009)